

TABLE—MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
	Deposition of a sample in a nationally recognized culture collection	R	TGAI	TGAI	--
885.1300	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	--
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	1
885.1500	Certification of limits	R	MP	EP	--
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	--
830.6303	Physical state	R	TGAI	TGAI	--
830.6304	Odor	R	TGAI	TGAI	--
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	--
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	--
830.6319	Miscibility	R	MP	EP	2
830.6320	Corrosion Characteristics	R	MP	EP	3
830.7000	pH	R	TGAI	TGAI	--
830.7100	Viscosity	R	MP	EP	4
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	--

(d) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides product analysis as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required to support registration of each manufacturing-use product and end-use product. This analysis must be conducted at the point in the production process after which there would be no potential for microbial contamination or microbial regrowth. For full registration, generally an analysis of samples is a compilation of batches, over a period of time, depending on the frequency of manufacturing.

2. Only required for emulsifiable liquid forms of microbial pesticides.

3. Required when microbial pesticides are packaged in metal, plastic, or paper containers.

4. Only required for liquid forms of microbial pesticides.

#### § 158.2130 Microbial pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the residue chemistry data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test appear in paragraph (d) of this section, and the procedures appear in paragraph (e) of this section.

(b) *Key.* R=required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to the individual tests in the following table:

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(c) *Table.* The following table shows pesticides residue. The test notes are the data requirements for microbial shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES RESIDUE DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Pat-terns	Test Substance Data to Support MP or EP	Test Notes
885.2100	Chemical Identity	CR	EP	1
885.2200	Nature of the Residue in plants	CR	EP	1
885.2250	Nature of the Residue in animals	CR	EP	1
885.2300	Analytical methods - plants	CR	TGAI	1
885.2350	Analytical methods - animals	CR	TGAI	1
885.2400	Storage Stability	CR	EP	1
885.2500	Magnitude of residue in plants	CR	EP	1
885.2550	Magnitude of residues in meat, milk, poultry, eggs	CR	EP	1
885.2600	Magnitude of residues in potable water, fish, and irrigated crops	CR	EP	1

(d) *Test notes.* The following test note is applicable to the data requirements for microbial pesticides residue as referenced in the last column of the table contained in paragraph (c) of this section.

1. Required when the results of testing:

i. Indicate the potential to cause adverse human health effects or the product characterization indicates the microbial pesticide has a significant potential to produce a mammalian toxin; and

ii. The use pattern is such that residues may be present in or on food or feed crops.

the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for microbial pesticides toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Pat-terns	Test Sub-stance	Test Notes
Tier I				
885.3050	Acute oral toxicity/ pathogenicity	R	TGAI	1
885.3150	Acute pulmonary tox-icity/pathogenicity	R	TGAI	--
885.3200	Acute injection toxicity/ pathogenicity/(intra-venous) Acute injection toxicity/ pathogenicity/ (intraperitoneal)	R	TGAI	2
885.3400	Hypersensitivity inci-dents	R	All	3
885.3500	Cell culture	R	TGAI	4
870.1100	Acute oral toxicity	R	MP , EP	1, 5
870.1200	Acute dermal toxicity	R	MP , EP	5

§ 158.2140 Microbial pesticides toxicology data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the toxicology data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (d) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (d) of this section, and apply to